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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,070	02/27/2002	Michael Robert West	PG3672	5324

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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	**PAPER NUMBER**
1641	9

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,070	WEST, MICHAEL ROBERT	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1--26* is/are pending in the application.

4a) Of the above claim(s) *1-4,9-18 and 23-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election on group II, claims 5-8, 19-22, with traverse has been received and entered on Paper No. 8. The traversal is on the ground(s) that group I having a technical feature applicable to group II-IV, therefore applicant is entitled to have four groups examined because there is an unity of invention. This is not found persuasive because each group possesses a special technical feature not sharing by other groups. (See detailed in the Election/Restriction Office Action sent on March 25, 2003)

The requirement is still deemed proper and is therefore made **FINAL**.

Abstract

Applicant is reminded that the acronym, i.e. COPD, used in the abstract language must be accompanied with a clear and whole meaning of the purported wordings, i.e. chronic obstructive pulmonary disease. Appropriate correction is needed.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5-8 and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 5, line 1, "COPD" needs to be spelled the full name for clarity.

With respect to claim 5, line 2, "soluble E-cadherin" is vague and indefinite. It is unclear what soluble applicant refers to. The specification describes the soluble E-cadherin as "some shedding of E-cadherin extracellular domain as *soluble fragment*." (See specification, page 3, line 27-28) It is unclear as to what constitutes "soluble" in the claimed language. Applicant needs to clearly point out where the definition of this "soluble" E-cadherin in the specification.

Similarly, claims 6-8 and 19-22 also share the same problem as to the "soluble E-cadherin" discussed in claim 5.

With respect to claim 5, "a method of treating a patient," is vague and confusing. The instant claim recites a method of "treating" a patient, whereas the essence of the instant claim does not support the purported treatment preamble. The instant claim merely recites method of "correlating" the concentration of E-cadherin in patient with COPD patients.

With respect to claim 5, line 4, "administering a compound" is vague and indefinite. It is unclear what compound applicant refers to. Additionally, what compound would ameliorate the symptoms of the disease.

With respect to claim 5, line 4, "ameliorate the symptoms of the disease" is vague and indefinite. It is unclear what symptoms applicant refers to.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 5-8, 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bullock et al. (J Allergy and Clinical Immunology (1998) 101: S111) in view of combination of Katayama et al. (International J. Oncology (1994) 5: 1049-1057; Abstract) and Cioffi et al. (Tumori (1999) 85: 32-34)

Bullock et al. teach using immunohistochemistry to investigate the distribution and expression of E-cadherin in pulmonary associated diseases, including COPD. Bullock et al found out that the higher expression of E-cadherin mirroring the pathological progression of the COPD diseases. (See abstract) However, Bullock et al. differs from the instant invention in not explicitly teaching measurement of E-cadherin level from patients' blood serum or urine samples and correlating the level to the FEV1. (See abstract) and treating COPD patients with a compound to ameliorate the symptoms.

Katayama et al. teach that soluble E-cadherin circulates in human body and can be used as a biomarker for detecting pulmonary dysfunctions. (See abstract) Similarly, Cioffi et al. also teach E-cadherin as a biomarker for lung cancer. (See abstract) Both Katayma et al. and Cioffi et al teach measuring E-cadherin from patients' urine and blood serum, respectively. (See abstracts)

Examiner noticed that applicant cited the commonly recognized techniques in the art (*American Thoracic Society Criteria*) for determining COPD, such as FEV1< 70% predicated. (See specification, pages 1-2) Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to (i) include monitoring or measuring the E-cadherin; (ii) from samples of urine and/or blood serum from COPD patients; (3) correlate the level of E-cadherin with FEV1 with a reasonable expectation of success. With respect to use a compound to ameliorate COPD patients, it only involves routine practice in the art since the essential step for the current invention is to identify the COPD patient by correlation with the E-cadherin with FEV1. Once the patient is identified, the subsequent treatment is obvious.

The motivation to do so would have been the recognition of the following:

(1) It is well recognized and commonly used in clinical for determining COPD by measuring FEV1 from COPD patients. (*American Thoracic Society Criteria)*
(2) E-cadherin is known for pulmonary dysfunction biomarker and circulates in the body, and can be detected in urine and blood serum.
(3) E-cadherin has been shown attributes to the COPD cellular pathological progression.
(4) Treating a patient with a particular agent for the specified disease is a routine practice in the art once the patient has been identified.

Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu
Examiner
Art Unit 1641

July 2, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
7/11/03